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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/223,957	12/31/1998	RODERIC M. K. DALE	OLIG-0004	4286

7590

07/30/2002

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EXAMINER

OWENS JR, HOWARD V

ART UNIT PAPER NUMBER

1623

DATE MAILED: 07/30/2002

*22*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicant(s)

09/223,957

Applicant(s)

DALE ET AL.

Examiner

Howard V Owens

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 6-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 6-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **Detailed Action**

The following is in response to the request for continued examination filed 11/30/01:

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(a) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/30/01 has been entered.

An action on the merits of claims 1, 3-4 and 6-21 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **Response to declaration**

In an interview with applicant's representative Dianna Devore on 7-28-00, a declaration was submitted in response to a request by Examiner Kunz showing why one of skill in the art would not have been motivated to use a C18 column with the solvent system and pH range set forth in the instant invention for the desalting oligonucleotides. Examiner Kunz set forth the references (Hatzenbuehler et al. 5,275,946 at column 6, lines 4 - 10; Padmapriya et al. 5,929,226,) containing the C18 column to support the

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assertion that the prior art clearly teaches the desalting of nucleic acids using a strongly hydrophobic matrix. The declaration was sufficient to overcome the prior art of Hatzenbuhler et al. and Padmapriya et al., however, neither Hatzenbuhler et al. nor Padmapriya is relied upon in this office action. The claims have been amended to a two stage process wherein the nucleic acid is purified through anion exchange chromatography with a subsequent purification through a hydrophobic polymeric medium. The point of novelty of applicant's invention is the binding of the nucleic acid to the hydrophobic medium and eluting the nucleic acid in a desired volume of an aqueous organic solvent. A 35 U.S.C. 103 rejection is set forth below addressing the amended claims and the purported novelty.

### **35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-4 and 6-21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Colpan et al. (Colpan), U.S. 5,747,663 in combination with Su, U.S. 5,804,684.

Claims 1-14, 18-21 are drawn to a method of desalting and concentrating a nucleic acid within a sample comprising anion exchange purification with subsequent purification with a strongly hydrophobic base matrix selected from the group consisting of polystyrene, polyethylene, polyvinyl and polypropylene.

Claims 16 and 17 are drawn to the method of claim 1 wherein the linkages of the nucleic acid are 3'-5' or 5'-2' and the sample is the product of either strong or weak anion exchange chromatography.

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Colpan teaches a method of purifying nucleic acids using a first step of anion exchange chromatography (col. 3, lines 40-50) with a subsequent purification using an inorganic materials such as polystyrene resins and copolymers thereof (col. 3, lines 23-67). Colpan further teaches that samples that are suitable for purification include nucleic acids such as RNA, YACs and genomic DNA obtained from cells, cell organelles, tissues or microorganisms (col.3, lines 65-67), which encompasses the claimed nucleic acid substrates (in either 3'-5' or 5'-2' forms) as well as the biological source.

While Colpan teaches the use of polymers such as polystyrene for the second purification step, it does not teach the use of the additionally claimed polymers such as polyethylene, polyvinyl and polypropylene.

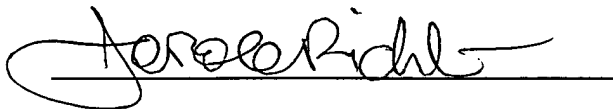
Su bridges the nexus between the prior art and the invention as claimed as it teaches that modified hydrophobic polymers such as polyethylene, polyvinyl and polypropylene are used in the purification of nucleic acids from biological samples (col.7, lines 40-54). Su teaches that these polymers are used in nucleic acid purification because digested proteins and salts do not bind to the polymeric matrix thus they are separated from the nucleic acid. Su also teaches that the binding of the nucleic acid is reversible since the binding is not through physical trapping, affinity binding or electrostatic interactions (col. 7, lines 3-17). One of skill in the art would recognize that this form of reversible binding would be conducive to easy removal of the nucleic acid through multiple aqueous washings.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use anion exchange chromatography and a hydrophobic polymer for desalting and purification of a nucleic acid sample.

A person of ordinary skill in the art would have been motivated to use anion exchange chromatography and a hydrophobic polymeric matrix such as polyethylene, polyvinyl, and polystyrene given the art recognized benefits of reversible binding of the nucleic acid sample while allowing contaminants such as digested proteins and salts to be removed.

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Howard V. Owens  
Patent Examiner  
Art Unit 1623

A handwritten signature in black ink, appearing to read "Johann Richter", is written over a horizontal line.

Johann Richter, Ph.D., Esq.  
Supervisory Patent Examiner  
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

The fax phone number for this Group is (703) 308-4556.